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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/711,784	11/13/2000	Chris De Bruijn		8210

28983 7590 08/01/2002

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EXAMINER

MCKANE, ELIZABETH L

ART UNIT	PAPER NUMBER
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1744

DATE MAILED: 08/01/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/711,784

Applicant(s)

DE BRUIJN ET AL.

Examiner

Leigh McKane

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-- **Th MAILING DATE of this communication appears on the cover sheet with the correspond nc address --**

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 46-57 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 46-57 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ 6) ☐ Other: ____

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 46-49 and 51 are rejected under 35 U.S.C. 102(e) as being anticipated by Hofmann et al (U.S. Patent No. 5,817,630).

Hofmann et al teaches a hydrogen peroxide-free ophthalmic solution containing 0.05 0.2% (500-2000 ppm) lipoic acid, a viscosity altering agent (polyvinyl alcohol), a sequestering agent (EDTA, etc.), a wetting agent (surfactant), and an osmotic agent (tonicity adjusting agent). See col.2, lines 31-32 and lines 37-41; col.3, lines 36-38 and lines 57-61.

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3. Claims 46, 48, and 49 are rejected under 35 U.S.C. 102(e) as being anticipated by Squires (U.S. Patent No. 6,355,684).

Squires discloses an ophthalmic composition containing echinacea extract in an amount of 0.2-60% (2000-600,000 ppm), a sequestering agent (EDTA), and a wetting agent (surfactant). See col.3, lines 35-41; col.4, lines 11-18, line 31, lines 62-64; col.6, lines 36-41.

4. Claims 52, 53, and 55 are rejected under 35 U.S.C. 102(b) as being anticipated by Medow et al (U.S. Patent No. 3,943,251).

Medow et al teaches an ophthalmic composition containing hydrastine or berberine, a wetting agent (lubricating agent), and a viscosity altering agent (thickening agent). See Abstract and col.1, line 32. The intended use "contact lens solution" of the instant claims does not patentably distinguish the claims from the prior art of record.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

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4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claim 50 is rejected under 35 U.S.C. 103(a) as being unpatentable over either Hofmann et al or Squires, both in view of Chiou (U.S. Patent no. 5,182,258).

Both Hofmann et al and Squires teach an ophthalmic composition employing surfactants but do not disclose using saponin as the surfactant. Chiou discloses an ophthalmic composition which may contain "surfactants such as saponins" (col.8, lines 64-65). As saponin is a surfactant safe for use in the eye, it would have been obvious to one of ordinary skill in the art to use a saponin as the surfactant of either Hofmann et al or Squires.

9. Claims 47 and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Squires in view of Laub (U.S. Patent No. 5,945,446).

Squires discloses an ophthalmic composition but does not teach an ophthalmic composition containing a viscosity altering agent or an osmotic agent. Laub teaches ophthalmic preparations including a viscosity altering agent (hydroxypropylmethylcellulose) and an osmotic agent (sodium chloride). As these are known additives for making ophthalmic preparations acceptable to the eye, they would have been obviously used in the composition of Squires.

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10. Claims 54 and 57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Medow et al in view of Laub.

Medow et al teaches an ophthalmic composition but fails to disclose a composition containing a sequestering or osmotic agent. Laub teaches ophthalmic preparations including a sequestering agent (edetate disodium) and an osmotic agent (sodium chloride). As these are known additives for making ophthalmic preparations acceptable to the eye, they would have been obviously used in the composition of Medow et al.

11. Claim 56 is rejected under 35 U.S.C. 103(a) as being unpatentable over Medow et al in view of Chiou.

Medow et al teaches an ophthalmic composition employing surfactants but does not disclose using saponin as the surfactant. Chiou discloses an ophthalmic composition which may contain "surfactants such as saponins" (col.8, lines 64-65). As saponin is a surfactant safe for use in the eye, it would have been obvious to one of ordinary skill in the art to use a saponin as the surfactant of Medow et al.

Conclusion

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leigh McKane whose telephone number is 703-305-3387. The examiner can normally be reached on Monday-Wednesday (7:15 am-4:45 pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert J. Warden can be reached on 703-308-2920. The fax phone numbers for the

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organization where this application or proceeding is assigned are 703-872-9310 for regular communications and 703-872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

Leigh McKane
Leigh McKane
Primary Examiner
Art Unit 1744

elm
July 29, 2002